Remarks

As a preliminary matter, please note the Information Disclosure Statement (IDS) submitted herewith.

Claims 3-11, 19-24, 32-40, 48-53, 60-68, 76-81, 88-91, 96-101, 108-111, 116-121, 128-131, 136-141 and 148-150 have been withdrawn from consideration due to the election-of-species requirement set forth in the Office Action mailed on April 11, 2003.

Claims 1-2, 12-18, 25-31, 41-47, 54-59, 69-75, 82-87, 92-95, 102-107, 112-115, 122-127, 132-135, 142-147, and 151-155 remain in the application.

Independent claim 1 has been currently amended by incorporating the subject matter of claims 16 and 17 therein. Claims 16 and 17 have accordingly been canceled. The dependency of claim 18 has been suitably changed to be from claim 1 so that it does not depend from a canceled claim. In addition to the specific polymers from claim 17 now recited in claim 1, the additional specific polymer carboxymethyl ethyl cellulose is now also recited therein. Support for this additional polymer is in the specification, for example at page 40, line 19.

In parallel fashion, independent claims 30, 58, 86, 106, and 126 have been currently amended. Correspondingly, claims 45 and 46, claims 73 and 74, claims 93 and 94, claims 113 and 114, and claims 133 and 134 have been canceled. Claims 47, 75, 95, 115, and 135 have been currently amended by changing their dependency.

Claims 103 and 123 have been canceled. The dependency of claims 104 and 124 has been suitably changed so that they do not depend from a canceled claim.

New dependent claims 156-163 have been added to cover embodiments wherein the drug is specifically ziprasidone. Support is in the specification, for example, at page 28, line 18. No additional claim fees are due for the new claims since at least an equal number of claims has been canceled.

The Examiner objected to the specification at page 3, line 20 due to the missing patent number. Applicants note that no U. S. patent has yet issued corresponding to WO 99/01120. It is requested that this issue be deferred for the present. When a US patent issues, Applicants will amend the specification to suitably reflect the US patent number. If no patent issues prior to the issuance of a patent on the instant application, Applicants will amend the specification to delete reference to a US patent.

Claims 146 and 155 stand rejected under 35 U.S.C. §112, second paragraph, the Examiner having stated that "...it is not clear how the aqueous solution is formed in a use environment such as in vitro and in vivo." Applicants interpret the Examiner's statement as an indefiniteness rejection, i.e., for failing to particularly point out and

distinctly claim the subject matter which Applicants regard as the invention. Applicants traverse the 35 U.S.C. § 112 rejection and request reconsideration by the Examiner.

Applicants submit that the claims are definite and that the rejection is misplaced.

The first sentence of the second paragraph of 35 U.S.C. §112 is essentially a requirement for precision and definiteness of claim language. If the scope of subject matter embraced by a claim is clear, and if an Applicant has not otherwise indicated that he intends that claim to be of a different scope, then the claim does particularly point and distinctly claim the subject matter which the Applicant regards as his invention." In Re Borkowski, 164 U.S.P.Q. 642, at 645-646 (C.C.P.A. 1970). §112, second paragraph thus calls for precision and definiteness, meaning that one skilled in the art must be able to tell with a reasonable degree of certainty whether his or her conduct is within or outside the scope of the claim. In the instant application, those skilled in the art well know what a "solution" is, such that claims 146 and 155 are clear and understandable. The Examiner has provided no basis why the term "solution" would not be clear and understandable. Applicants accordingly respectfully submit that as such, they are in compliance with 35 U.S.C. §112, second paragraph.

Per paragraphs 7 and 8 of the Office Action, claims 1, 2, 12-18, 25-31, 41-47, 54-59, 69-75, 82-87, 92-95, 102, 105-107, 112-115, 122, 125-127, 132-135 and 142-145 were rejected under 35 U.S.C. 102(b) as being anticipated by Okada et al. (US 5,496,561). The Examiner stated, in pertinent part:

> Okada discloses a controlled release pharmaceutical composition comprising crystalline form of a drug (column 3, line 32); polymer such as hydroxypropylmethylcellulose acetate succinate, hydroxypropylmethylcellulose phthalate, cellulose acetate phthalate and carboxymethylethyl cellulose (column 3, lines 36-39, column 4, lines 20-25); plasticizers such as triethyl citrate, triacetin, polyethylene glycol, castor oil, polysorbitan monooleate, glycerine fatty acid ester (column 5, lines 5-8).
>
> The instant application claims a composition that comprises a drug in a pharmaceutically acceptable solubility-improved form and a concentration-enhancing polymer is a salt and several examples of drugs that are suitable in the instant invention are listed in the specification (page 30, line 31 to page 31 line 5, page 35, line 13 to page 36 line 26 and page 26, line 30 to page 29 line 18). In the instant application, the recitation that the composition achieves a maximum equilibrium concentration of at least 1.25 fold of a drug ... is a property of the drug composition and property of a composition is not separable from the composition; and thus the composition of the prior art would inherently achieve said equilibrium concentration relative to the drug.
>
> Instant claims 25-28, 30, 54-57 and 82 recite the property of the composition and the teaching of Okada meets the limitations of said claims; diclofenac, which is one of the drugs disclosed in Okada has analgesic, anti-inflammatory and antipyretic activities; and thus Okada meets the limitation of instant claim 29. The method of the instant claims administers the drug and the concentration-enhancing polymer and the prior art teaches administering the composition to a patient/subject in need thereof.

The rejection is traversed, particularly in light of the claims as now amended. Okada nowhere discloses, nor does Okada describe, even generally, a composition comprising a drug in a solubility-improved form and a cellulosic ionizable polymer, much less a polymer that is a member of the group required by all of Applicants' claims. In those few instances in which Okada does disclose the use of other than the free form of a drug (e.g., such as salts in his Examples 7 and 9), Okada does not disclose the use of a cellulosic ionizable polymer, but rather teaches using something completely different such as corn starch. It is well settled law that the standard for anticipation is one of strict identity, meaning that for prior art to anticipate, it must contain all of the essential elements. Hybritech Inc. v. Monoclonal Antibodies, Inc. 231 USPQ 81 (Fed Cir 1986). if a reference does not disclose all elements and/or limitations of an applicant's claims, that reference can not be anticipatory. Gechter v. Davidson, 43 USPQ2d 1030 (Fed. Cir. 1997).

> Under 35 USC §102, every limitation of a claim must identically appear in a single prior art reference for it to anticipate the claim. [43 USPQ2d at 1032].

Because Okada nowhere discloses or describes a composition comprising a solubility-improved form of a drug and one of the cellulosic ionizable polymers also required by Applicants' claims, Okada does not disclose the elements of Applicants' claims, and Okada accordingly does not anticipate. Gechter, supra. Withdrawal of the rejection is accordingly respectfully requested.

Per paragraph 8, claims 1, 2, 12-14, 16, 25-31, 41-43, 45, 54-59, 69-71, 73, 82-87, 93, 102, 105-107, 113, 122, 125-127, 133 and 142-145 were rejected under 35 U.S.C. 102(b) as being anticipated by Piergiorgio et al. (US 4,880,623). The Examiner stated, in pertinent part:

> Piergiorgio teaches a composition comprising nifedipine (an anti-hypertensive), polyethylene glycol, hydroxypropylmethyl cellulose and other excipients (abstract and example 2). Piergiorgio, teaches that the bioavailability of the drug in the above composition is highly increased. The polymers of the prior art fall within the scope of the polymers that applicants regard as "concentration enhancing." The method of the prior art administers the drug with the concentration-enhancing polymer and the prior art meets the limitation because the prior art administers the composition to a subject in need thereof.
>
> Applicants' traversal of the rejection centers on the argument that Piergiorgio's polymers are not used to enhance concentration but rather are used as "a matrix which adds additional sustained release characteristics to a formulation which is already sustained release." Thus, applicants argue, one

skilled in the art would not use the polymers of the prior art to enhance bioavailability or concentration of drugs.

Applicants' arguments filed 04/15/02 have been fully considered but they are not persuasive.

The claims are directed to a composition comprising a drug and a polymer that applicants have labeled "concentration enhancing." The polymers of the prior art fall within the scope of the polymers that applicants regard as "concentration enhancing." Applicants provided no data showing that the polymers disclosed and taught by Piergiorgio would not enhance drug concentration.

The rejection is traversed in light of Applicants' amended claims. Piergiorgio is directed to a composition comprising nifedipine and polyethylene glycol. Piergiorgio does not disclose, teach, or suggest a composition comprising a drug in a solubility-improved form and a cellulosic ionizable polymer. In fact, Piergiorgio does not disclose any cellulosic ionizable polymers, period. Accordingly, an anticipation rejection cannot lie because Piergiorgio does not disclose or teach all of the elements of Applicants' claims. Gechter, supra. Withdrawal of the rejection is accordingly respectfully requested.

Per paragraph 10, claims 15, 17, 18, 44, 46, 47, 72, 74, 75, 92, 94, 95, 112, 114, 115, 132, 134 and 135 were rejected under 35 U.S.C. 103(a) as being unpatentable over Piergiorgio et al. (US 4,880,623). The Examiner stated:

Piergiorgio discloses the composition and method of the instant claims except that Piergiorgio does not teach the polymer recited in the above claims. However, one concentration-enhancing polymer can substitute for another concentration enhancing polymer. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare the drug composition of Piergiorgio et al. (US 4,880,623). One having ordinary skill in the art would have been motivated to substitute one concentration-enhancing polymer with another with the expectation of enhancing the concentration of the drug in the use environment.

The rejection is traversed on the basis that Piergiorgio clearly does not support obviousness. Applicants' claims can not be obvious over Piergiorgio when Piergiogio (1) discloses none of the specific cellulosic ionizable polymers required by Applicants' claims and (2) discloses nothing relating to concentration enhancement. Piergiorgio teaches that:

...According to the present invention, in fact, a solution of nifedipine and polyethylene glycol of high molecular weight is made in a common solvent (or mixture of solvents) and the solution is dispersed on a micronized inert excipient which is soluble in the gastrointestinal juices.

> The surfactant property of the polyethylene glycol of high molecular weight is therefore exploited so as to be able to "wet" the microparticles of the inert excipient with the solution, and spread it over all of the very high surface available so that, when the solvent evaporates, the nifedipine crystals which precipitate are tiny and remain as such due to the impossibility of swelling or aggregation between each other. [Piergiorgio Column 2, lines13-26]

There is simply nothing in Piergiorgio relevant to increasing the concentration of drugs. Indeed, the above quotation teaches away from any consideration of increased solubility. Piergiorgio uses polyethylene glycol for its surfactant properties. He states he is exploiting those surfactant properties to wet the microparticulate excipient he also uses, meaning that he is not interested in affecting solubility. His focus on surfactant properties and wetting constitutes one reason why the rejection should be withdrawn. That is, it cannot be obvious to substitute one concentration-enhancing polymer for another, as alleged by the Examiner, from a reference that neither discloses, describes or in any way addresses anything relating to concentration enhancement. Only Applicants own specification addresses concentration enhancement, but Applicants' own specification cannot be used to support the Examiner's statements. In order for an obviousness rejection to lie, the prior art must in some way supply a suggestion to do that which Applicant has invented, and must also provide a reasonable expectation of success. American Hospital supply Corp. v. Travenol Laboratories, Inc., 223 USPQ 577, 582 (Fed. Cir. 1984). The Federal Circuit has explained the proper test:

> The consistent criterion for determination of obviousness is whether the prior art would have suggested to one of ordinary skill in the art that this process should be carried out **and would have a reasonable likelihood of success,** viewed in light of the prior art. **Both the suggestion and the expectation of success must be founded in the prior art, not in the applicant's disclosure** (emphasis added).

In re Dow Chemical Co., 5 USPQ.2d 1529, 1531 (Fed. Cir. 1988); Amgen, Inc. V. Chugai Pharmaceutical Co. Ltd. 18 USPQ.2d 1016. 1022-23 (Fed. Cir.), cert. denied, 502 U.S. 856 (1991). Clearly Pirgiorgio, who says nothing relating to increasing solubility or using Applicants' concentration-enhancing polymers, contains no such suggestion, let alone supplying any expectation of success. It is accordingly respectfully submitted that the rejection should be withdrawn because Piergiorgio clearly satisfies none of the legal elements required to support obviousness.

Claims 1, 16-18, 25-28 and 30 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3, 6, 7, 10 and 12-14, of copending Application No. 10/176462. The Examiner stated that, although the conflicting claims are not identical, they are not patentably

distinct from each other because the solubility-improved drug in the co-pending application as recited in lines 22-25 is encompassed in the broad solubility improved drug of the examined application.

The rejection is traversed on the basis that it is not supported by the relevant facts. It is noted that the usual means for overcoming an obviousness-type double patenting rejection is by submitting a terminal disclaimer to disclaim the terminal portion of any patent that issues on the instant application. The terminal disclaimer avoids any timewise extension of a second existing patent or application (in this case, Appln. No. 10/176462, the double patenting reference). A disclaimer that disclaims the terminal portion of a patent that issues on the instant application is not needed, however, since no patent issuing on instant application could provide any timewise extension for Appln. No. 10/176462. Any patent issuing on the instant application will nominally expire twenty years from the application's original date of filing, i.e. on December 20, 2020. But, the aforementioned expiration date occurs **before** the expiration of any patent issuing on Appln. No. 10/176462, which will expire on June 20, 2022. Because the patent issuing with the instant claims will expire before any patent issuing on Appln. No. 10/176462, it can provide no timewise extension. Thus a terminal disclaimer is not needed, and the double patenting rejection should therefore be withdrawn.

For the sake of completeness, it is noted that there is no basis for double patenting going the other way, either. That is, the claims of Appln. No. 10/176462 cannot be obvious over the claims of the instant application. The claims of Appln. No. 10/176462 recite compositions that require, *inter alia*, a specific solubility-improved drug form. None of the solubility-improved drug forms required by the claims of Appln. No. 10/176462 is disclosed or suggested in the claims of the instant application. Without such a suggestion, obviousness simply cannot lie, as explained above.

The observation raised by the Examiner relating to replacing "cellulosic" with "cellulose" is noted. It is requested that the observation be withdrawn and that no requirement to replace "cellulosic" with "cellulose" be made. The term "cellulosic" is well understood by those skilled in the art. Applicants have expended a great deal of definitional and explanatory text in the specification to ensure that there is no doubt as to the exact meaning of "cellulosic". The term has been used consistently throughout the specification and the claims. In view of such extensive explanation, definition, and consistent use, it is submitted that there are no clarity

issues in respect of "cellulosic", and the Examiner has provided no basis otherwise. Further, it is well accepted that an applicant can define his own terms, i.e. he can be his own lexicographer. See Beachcombers, International, Inc. v. WildeWood Creative products, Inc., 31 USPQ2d 1653, at 1656 (Fed Cir 1994) where the court stated:

> As we have repeatedly said, a patentee can be his own lexicographer provided the patentee's definition, to the extent it differs from the conventional definition, is clearly set forth in the specification

Thus, as a threshold consideration Applicant was clearly permitted to use the phrase "cellulosic", particularly since he went out of his way to define the term.

In view of the foregoing comments and amendments, this case is believed to be in condition for allowance, and a Notice of Allowance is courteously solicited.

Respectfully submitted,

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